



PATENT
1049-1-004N2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : LITTMAN *ET AL.*
SERIAL NO. : UNASSIGNED EXAMINER : UNKNOWN
FILED : HEREWITH ART UNIT : UNKNOWN
FOR : G-COUPLED RECEPTORS ASSOCIATED WITH
MACROPHAGE-TROPIC HIV, AND DIAGNOSTIC AND
THERAPEUTIC USES THEREOF

PRELIMINARY AMENDMENT

Assistant Commissioner For Patents
Box PATENT APPLICATION
Washington, D.C. 20231

Dear Sir:

In accordance with Rule 111 of the Rules of Practice please consider the following amendments and remarks. Please amend the Application as follows:

IN THE SPECIFICATION:

On Page 1, line 9, please replace:

“ CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a Continuation-In-Part of Copending Application Serial No. unassigned filed May 19, 1997 which is based on Provisional Application Serial No. 60/017,157, filed May 20, 1996, by the inventors herein. Priority is claimed under 35 U.S.C. §120 as to the earlier filed applications, and the disclosures thereof are incorporated herein by reference.”

with

- - CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a Continuation of Copending Application Serial No. 08/861,105

filed May 21, 1997, which is a Continuation-In-Part of Application Serial No. 08/858,660 filed May 19, 1997, now abandoned, which is based on Provisional Application Serial No. 60/017,157, filed May 20, 1996, and Provisional Application Serial No. 60/020,043 filed June 19, 1996. Applicants claim the priority of these Applications under 35 U.S.C. §§120 and 119(e). The disclosures of the Applications having the Serial Nos. 08/861,105, 08/858,660 and 60/017,157 are hereby incorporated by reference in their entireties. - -

On Page 10, line 23, after "conformational" please replace "isotope" with - - epitope - - , therefor.

On Page 14, line 20 after "FIGURE" please replace "1 shows" with -- 1A-1B show -- therefor;

on line 22 after "Envs" please insert -- (Fig. 1B) -- therefor, and after "Env" please insert -- (Fig. 1A) -- therefor;

on line 26 after "FIGURE" please replace "2 shows" with -- 2A-2C show -- therefor; and

on line 33 after "Figure" please replace "2a," with -- 2A - - therefor.

On Page 15, line 3, after "Figure" please replace "2b," with -- 2B - - therefor;

on line 4 after "as in" please replace "2a," with -- Figure 2A - - therefor;

on line 5 please replace "2c is the same as 2a" with - - Figure 2C is the same as Figure 2A - - therefor;

on line 8 after "FIGURES" please replace "3a-3d" with -- 3A-3G -- therefor;

on line 11 please replace "3a" with -- 3A -- therefor;

on line 15 after "Figure" please replace "3b shows" with -- 3B-3E show -- therefor;

on line 22 after "Figure" please replace "3c" with -- 3F -- therefor, and after "HOS.CD4 cells (human osteosarcoma," please insert - - which has been deposited with the American Type Culture Collection, Rockville Md., 20852 on May 25, 2000 under the Budapest Treaty - -;

on line 23 after "Figure" please replace "3d" with -- 3G -- therefor;

and

on line 27 after "FIGURE" please replace "4 illustrates" with -- 4A-4D
illustrate -- therefor.

On Page 16, line 1 after "FIGURE" please replace "5" with -- 5A-5D - - therefor; and
line 2, after "Figure" please replace "5a depicts" with -- 5A-5C depict the
results when - - therefor; and

on line 14 after "FACScaliber." please replace "5b," with -- Figure 5D shows
the - - therefor.

On Page 48, line 3, after "Fig." please replace "1" with - - 1A-1B - - therefor;
on line 5, after "Fig." please replace "1" with - - (1A-1B) - - therefor;
on line 16, after "Fig." please replace "2a" with - - 2A - - therefor;
on line 19, after "Fig." please replace "2a" with - - 2A - - therefor;
on line 22, after "Fig." please replace "2a" with - - 2A - - therefor;
on line 26, after "Fig." please replace "2b" with - - 2B - - therefor; and
on line 27, after "Fig." please replace "2c" with - - 2C - - therefor.

On Page 49, line 3, after "Fig." please replace "3a" with - - 3A - - therefor;
on line 5, after "Fig." please replace "3a" with - - 3A - - therefor;
on line 6, after "Fig." please replace "3a" with - - 3A - - therefor;
on line 8, after "Fig." please replace "3b" with - - 3B-3E - - therefor;
on line 12, after "Fig." please replace "3a" with - - 3A - - therefor;
on line 21, after "Fig." please replace "3c, 3d and data not shown" with
- - 3F-3G - - therefor;
on line 23, please replace "3d" with - - 3G - - therefor; and
on line 25, please replace "3d" with - - 3G - - therefor.

On Page 50, line 4, after "Fig." please replace "4" with - - 4A-4D - - therefor;
on line 18, after "Fig." please replace "5a" with - - 5A - - therefor;
on line 23 after "infection" please insert - - Fig. 5B - - therefor;
on line 24, after "Fig." please replace "5b" with - - 5C - - therefor; and

on line 26, after "Fig." please replace "5c" with - - 5D - - therefor.

On Page 53, line 25 after "whereas" please replace "virtues" with - - viruses - -, therefor.

IN THE CLAIMS:

Please cancel Claims 27-32 and 41-60 without prejudice.

Please amend the Claims as follows:

37. (Amended) [An assay for] A method for selecting for [a suspected therapeutic] an agent for possible use in the treatment and/or prevention of AIDS [with the use of the cell of Claim 27] which comprises:

(a) [administering a potential therapeutic] contacting an agent with [to said] a cell in the presence of an HIV virus or a virus pseudotyped with a macrophage-tropic envelope; wherein in the absence of the agent said cell undergoes fusion with and/or permits entry to the HIV virus or the virus pseudotyped with a macrophage-tropic envelope; wherein CCR5 is a component of the surface of said cell; and wherein said fusion or entry is mediated by CCR5;

(b) [infecting said cell with a the HIV virus or the virus pseudotyped with a macrophage-tropic envelope;

(c)] measuring the ability of said cell to resist fusion with and/or permit entry to the HIV virus or the virus pseudotyped with a macrophage-tropic envelope [said infection]; and

[(d)] (c) selecting [the potential therapeutic] the agent when the measured ability of said cell to resist [said infection] fusion with and/or entry to the HIV virus or the virus pseudotyped with a macrophage-tropic envelope is statistically greater in the presence of the [said potential therapeutic] agent than in the absence of [said potential therapeutic] the agent [; wherein said selected potential therapeutic agent is a suspected therapeutic agent].

Please add the following Claims:

- - 70. The method of Claim 37 wherein the method further comprises:

(d) contacting the agent with CCR5; and

(e) determining if the agent binds to CCR5; wherein an agent that binds CCR5 is selected; and wherein steps (d) and (e) can be performed either prior to or after steps (a)-(c).

71. An antibody that is specific for an epitope of CCR5 that becomes accessible upon the binding of CCR5 with CD4 and/or an envelope protein of HIV-1.
72. An antibody that reacts with a shared epitope, wherein the shared epitope is formed by CCR5 binding an envelope protein of HIV-1, and/or CD4.
73. The antibody of Claim 72 that is a chimeric antibody.

REMARKS

The Applicants have amended the Specification to update the cross-reference to related applications, to indicate that the specified cell line has been deposited with the American Type Culture Collection, under the Budapest Treaty, and to correct typographical errors. Support for the amendment to Claim 37 and for New Claims 70-73 can be found throughout the Application as filed including in the original claims. Further support for the amendment to Claim 37 and New Claim 70 can be found on line 21 of Page 7 through line 2 of Page 8, on lines 16-20 of Page 8, on Page 13, lines 20-22, on Page 14, lines 27 and 28, on line 27 of Page 15, on Page 16, lines 1 and 2, on line 15 of Page 38 through line 5 of Page 41, and on line 30, of Page 49 through line 9 of Page 50. Further support for New Claims 71-73 can be found on Page 10, lines 23-29, and on line 19 of Page 33 through line 12 of Page 38. No new matter has been entered.

The Applicants respectfully request entry of the foregoing amendment into the file history of the above-identified Application being filed herewith. Early and favorable action on the pending set of Claims is earnestly solicited.

No additional fees are believed to be necessitated by the foregoing amendments.
However, should this be erroneous, authorization is hereby given to charge Deposit Account
No. 11-1153 for any underpayment, or credit any overages.

Respectfully submitted,



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Date: December 11, 2000

AMENDED OR NEW CLAIMS

37. (Amended) A method for selecting for an agent for possible use in the treatment and/or prevention of AIDS which comprises:

(a) contacting an agent with a cell in the presence of an HIV virus or a virus pseudotyped with a macrophage-tropic envelope; wherein in the absence of the agent said cell undergoes fusion with and/or permits entry to the HIV virus or the virus pseudotyped with a macrophage-tropic envelope; wherein CCR5 is a component of the surface of said cell; and wherein said fusion or entry is mediated by CCR5;

(b) measuring the ability of said cell to resist fusion with and/or permit entry to the HIV virus or the virus pseudotyped with a macrophage-tropic envelope; and

(c) selecting the agent when the measured ability of said cell to resist fusion with and/or entry to the HIV virus or the virus pseudotyped with a macrophage-tropic envelope is statistically greater in the presence of the agent than in the absence of the agent.

70. The method of Claim 37 wherein the method further comprises:

(d) contacting the agent with CCR5; and

(e) determining if the agent binds to CCR5; wherein an agent that binds CCR5 is selected; and wherein steps (d) and (e) can be performed either prior to or after steps (a)-(c).

71. An antibody that is specific for an epitope of CCR5 that becomes accessible upon the binding of CCR5 with CD4 and/or an envelope protein of HIV-1.

72. An antibody that reacts with a shared epitope, wherein the shared epitope is formed by CCR5 binding an envelope protein of HIV-1, and/or CD4.

73. The antibody of Claim 72 that is a chimeric antibody.

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APPLICANTS : Littman *et al.*
SERIAL NO. : 08/861,105 EXAMINER : R. Budens
FILED : May 21, 1997 ART UNIT : 1645
FOR : G-COUPLED RECEPTORS ASSOCIATED WITH
MACROPHAGE-TROPIC HIV, AND DIAGNOSTIC AND
THERAPEUTIC USES THEREOF

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231 on July 6, 2000.

Michael D. Davis, Reg. No. 39,161
(Name of Registered Representative)

Betty Schutt 7/6/00
(Signature and Date)

DECLARATION UNDER 37 C.F.R. § 1.808

Assistant Commissioner for Patents
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All restrictions imposed by the depositor on the availability to the public of the material deposited under the Budapest Treaty, with the exception of those permitted under 37 C.F.R. § 1.808(b), hereby are to be irrevocably removed upon the granting of the patent.

Respectfully submitted,
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